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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,796	07/14/2003	James C. Wickstead	291126/0004	7319

7590 11/30/2005

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EXAMINER
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FAYYAZ, NASHMIYA SAQIB

ART UNIT	PAPER NUMBER
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2856

DATE MAILED: 11/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

EK

<b>Office Action Summary</b>	<b>Application No.</b> 10/618,796	<b>Applicant(s)</b> WICKSTEAD ET AL.	
	<b>Examiner</b> Nashmiya S. Fayyaz	<b>Art Unit</b> 2856	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4 and 6-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nason- U.S. Patent # 5,869,003. As to claims 1-4 and 6-13, Nason discloses a self contained diagnostic test unit including a buffer container (reagent cap 16) with an interior 49', buffer fluid 48' and a weakened portion 39', a test strip 20 held by securement 56 which holds an "end" of the strip, a test strip container (18, 70, 76), a sample collector 12 for holding a sample 14/24 and shaped to receive buffer container 16 and having channeling member 64 with a lumen (outlet channel 66) wherein when the buffer container is squeezed as in embodiment of Fig. 8, membrane 39' is ruptured and reagent mixes with the sample from the lumen 66 to the wick 82 (also being held by securement 56) to the test strip 20, note figs. 1,2, 8 and 11-12 and col. 4, lines 4 et seq. Further, it is noted that Nason indicates the usage of a wick in Figs. 1 and 2 rather than a "filter". However, in the description of fig. 16, the wick 282 is also referred to as a

"transfer filter". Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have recognized that the wick 82 of Figs. 1 and 2 perform an inherent filtering function given the description of the wick 282 as a **transfer filter** in the Fig. 16 description and see col. 9, lines 48 et seq.

and hence designated the wick 82 as a filter. As to claim 2, it appears that the test strip 20 is perpendicular to the wick filter 82, note fig. 4. As to claim 3, it appears that buffer container is press fit over the sample collector. Official notice is taken that usage of threading on either element in lieu of a press fit is old and well-known. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have substituted threading on either element for the press-fit as a clear matter of design choice equivalent in operation. As to claim 4, note projection sleeve 34' engaging collector outer surface in fig. 8. As to claims 6-7, note membrane seal 39' and compressible bulb 30'. As to claim 8, note window 28. As to claims 9-10, note sleeve 70 and plug 76. As to claim 11, note the associated method described with the apparatus of claim 1 in col. 6, lines 5 et seq. and that the filter 82 has test strip 20 secured to the filter via securement 56. As to claims 12-13, note that nib 40' appears to act as a piercing member when the bulb is urged downward and compressed, note figs. 8-10.

2. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nason in view of Weiler et al- U.S. Patent # 5,121,856. . As to claim 5, the bulb 30' is not bellowed. However, in a related prior art device, Weiler et al disclose a

dispensing vial with bulb 127 in the form of a bellows-type cylinder 129 upon which there is placed a longitudinal compressive force, see fig. 9. Therefore, inclusion of such a bellows-type bulb would have been obvious to one of ordinary skill in the art at the time of the invention to have included in the Nason device as a known alternative to the squeezing of the sides of the bulb.

### ***Response to Arguments***

3. Applicant's arguments filed 9/9/05 have been fully considered but they are not persuasive. Applicant has argued 1) that the wick in Nason is merely a sponge whose only function is to wick liquid and the filter of the present invention acts to control flow of liquid and filter impurities and 2) the filter functions to "hold the test strip in place the chamber of the test strip container and the filter includes a securement that "fastens the test strip and holds it in place, gripping it on several surfaces".

Such arguments are not found persuasive because 1) the porous sponge wick 82 does perform a filtering function as is evident from the description of the wick 282 in Fig. 16 which refers to the *wick* in the alternative as a "transfer filter", see col. 9, lines 48 et seq. clearly indicating that the wick can be referred to as a wick or a filter and 2) it is noted that there is ***no claim language*** reciting that the filter hold the test strip in place or fastens the test strip, gripping it on several surfaces. The claims merely recite the filter *having a securement* and a test strip *having an end*

*held by said securement* or the filter "having a test strip secured thereto". These limitations are clearly met by securement 56 of Nason.

### ***Conclusion***

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashmiya S. Fayyaz whose telephone number is 571-272-2192. The examiner can normally be reached on Mondays and Thursdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron E. Williams can be reached on 571-272-2208.

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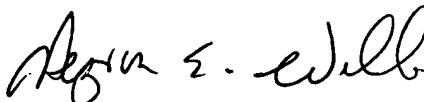
The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



NFayyaz  
Examiner  
Art Unit 2856

nf  
11/14/05



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